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METHOD AND APPARATUS FOR TRANSMITTING LASER RADIATION, INCLUDING TRANSMISSION OF RADIATION IN A HOLLOW BEAM CONFIGURATION, INTO A CONFINED TARGET SPACE

TECHNICAL FIELD

The present invention relates to devices and procedures for the controlled delivery of laser energy through an optical fiber. The present invention is especially suitable for treating a site on the surface of, or inside, a patient's body, with laser energy in a ring or hollow beam configuration, with little or virtually none of the light energy being emitted in the center of the ring or hollow beam.

BACKGROUND OF THE INVENTION AND TECHNICAL PROBLEMS POSED BY THE PRIOR ART

Articulated arms using an arrangement of mirrors, optical microscopes and other devices have been developed for delivering laser energy to the surface of a patent's body. Flexible, optical fibers are used to convey laser energy in surgery to tissue or into a confined space. Fibers can also be advanced through an artery or other body lumen or cavity, an endoscopic device, or a surgically created passage, to a selected internal treatment location. In certain medical applications, such devices include, or are incorporated in, catheters for transmitting the radiation to internal body sites.

Medical instruments of the above-described type may be broadly defined as fiber delivery systems. As used in this specification and in the claims, the term "fiber system" or "system" is intended to include broadly flexible, or rigid, instruments for directing laser energy to a target site on the body's surface or

an internal target through a natural or surgically created internal lumen, passage, or cavity.

A lens can be used to transmit the radiation from the laser into the optical fiber. For example, U.S. Patent No. 4,729,621 teaches the use of a cone-coupler having a wide proximal end for receiving radiation from the laser and having a narrow distal end which is optically coupled to the input end of the optical fiber. The input end of the fiber is generally flat and perpendicular to the optical axis of the lens or coupling system. The laser energy is transmitted from the lens, into the optical fiber, and is emitted from the distal end of the fiber where it may be directed against the selected target site.

A number of designs have been proposed for a fiber system which can be inserted into a body passage and operated to direct the laser radiation laterally to the surrounding site in the body cavity. While laser energy emitted from an optical fiber generally strikes the tissue as a "spot", beveling or changing the distal surface of the optical fiber can modify the impinging energy pattern. Some designs employ an internally reflecting prism for directing the radiation laterally. By removing the cladding from a portion of the optical fiber, radiation can be transmitted as a generally 360° beam radiating outwardly from the axis of the fiber. See, for example, U.S. Patent No. 4,672,961, Nos. 4,852,567, and No. 4,799,479.

Aiming a laser beam for use in surgery typically produces a spot irradiation zone on the target tissue. In the case of a Helium-Neon or "HeNe" aiming beam, the spot is red. As a result, tissue in the spot appears red, thus blood vessels within the spot can be seen only poorly.

While the above-discussed designs may operate

satisfactorily in the particular applications for which they are intended, it would be desirable to provide an improved fiber optic system for laser delivery in ophthalmology, angioplasty, surgery, or even manufacturing wherein the laser radiation could be directed to the site in a controlled manner. In particular, in some applications it would be desirable to emit a laser beam so as to produce a target tissue irradiation zone having an annular, ring or hollow conical beam pattern.

It would also be advantageous if such a device could be adapted for use with relatively higher power lasers in annealing the inner surfaces of tubes, cutting circles in materials, and other applications in which a defined closed loop, e.g., a ring, of laser energy could be effectively employed.

Preferably, such an improved device is not bulky or unduly complex. It would be advantageous if a relatively simple and small structure could be provided for use as, or in, a catheter or other device to be inserted within a confined space.

It would also be desirable to provide an improved method for irradiating sites, such as surgical sites, to effect a desired surface configuration of the tissue or other material at the site. The present invention provides a unique method for treating such sites with radiation in a controlled manner.

The present invention also provides an improved laser delivery method and fiber optic delivery system suitable for coupling to a laser source to direct a beam of laser energy in a controlled manner to a selected site, including in the form of a hollow cone or ring of laser energy. The present invention can accommodate various apparatus designs having the above-discussed benefits and features.

SUMMARY OF THE INVENTION

The present invention can be embodied in a fiber optic system, a medical device or an industrial tool for applying laser energy in a controlled manner, including pulsed as well as continuous wave forms, as a hollow beam of radiant energy to a selected site. The present invention can also be embodied in a method of so applying such energy.

In accordance with one aspect of the invention, a majority of the laser energy transmitted along one or more optical fibers is emitted or dispensed at the distal end of the optical fiber or fibers as a hollow cone or cylinder to form a laser energy ring at a plane substantially perpendicular to the longitudinal axis of the optical fiber at the distal end thereof. By changing the angle of inclination of the beam axis relative to the incident surface, radiation patterns resembling various conical sections, e.g., oval, parabolic, hyperbolic, elliptical, or circular, can be readily generated. By moving the distal end of the fiber system closer or further away from the target site, the size of the irradiated region can be changed at will. In this manner, laser energy may be applied in a precise and controlled manner to the site for performing medical procedures. Thus, the present invention is eminently well suited for sculpting the surface of a cornea to a desired smooth contour, among other things.

One preferred form of the apparatus of this invention employs an elongated, laser energy transmitting conduit in the form of a solid, cylindrical optical fiber. The fiber has a proximal end portion extending along a longitudinal axis. A beam of laser energy impinges on the proximal end surface of the fiber at an oblique angle. The proximal end portion of the

fiber usually includes a beveled, proximal end surface oriented at an oblique angle relative to the proximal end longitudinal axis for receiving the laser radiation, preferably an angle of 30° to 60°, and most preferably about 45°. The fiber has a distal end portion disposed adjacent the site to be treated (which may be in a confined space, e.g., a lumen or cavity) and has a distal end surface for emitting the laser radiation.

A focusing lens is provided with a mounting means for holding the lens and the fiber proximal end portion in a particular alignment. The optic axis of the lens is either generally parallel to, or coincident with, the proximal end longitudinal axis of the fiber, and the lens is focused on the fiber proximal end surface. A suitable laser energy source, emitting laser energy in a pulsed or continuous wave mode, is coupled to the lens. The laser radiation passing through the lens is transmitted into the fiber, reflected internally along the circumference of the fiber, and is emitted from the fiber distal end surface in a substantially hollow cone configuration which can be advantageously employed at selected sites, whether such sites are free of liquid or not.

One method aspect of this invention contemplates the positioning of a distal end portion of a cylindrical, solid, optical fiber opposite a target tissue on the surface of a patient or in a confined space. The proximal end portion of the fiber is provided with a beveled end surface oriented at an angle, relative to the proximal end longitudinal axis, for receiving the laser radiation. The radiation is focused on the beveled proximal end surface through a focusing lens that is positioned relative to the proximal end surface with the optic axis of the lens oriented generally parallel to the proximal end

longitudinal axis so that the laser radiation passing through the lens is transmitted into the fiber, reflected internally along the circumference of the fiber, and emitted from the fiber distal end surface in a substantially hollow cone configuration at a selected site. In this manner, coagulation, ablation, or vaporization, as well as cutting in a circular configuration can be effectively performed at the site.

The optical fiber can also be moved to reduce or increase the size of the emitted radiation pattern. Further, tissue or tissues can be shaped or sculpted by emitting the laser energy at various energy levels for predetermined periods of time at selected and/or varying distances from the target tissue.

A further aspect of the invention involves light energy at a wavelength which cannot be or is poorly transmitted through conventional optical fiber and entails a means for causing a laser to emit light energy in a ring-like, or hollow cone, beam which is conducted through a path-defining means to the target site. The path-defining means may include a microscope-like device with mirrors, or an articulated arm with mirrors, for changing the direction of the radiation relative to the direction of emission from the laser. Such laser emission is generally referred to as a TEM_{01^*} beam mode.

A further aspect of the invention accommodates variation of the radiation intensity with respect to circumferential or angular locations on the ring. Owing to material imperfections, manufacturing tolerances, operational variations, and the like, the intensity of the radiation at one angular location on the target ring pattern may be more or less than at another location on the ring. In order to provide a substantially uniform, average radiation intensity, over a period of time, for

any location in the ring, means are provided for angularly displacing at least a portion of the length of the optical fiber about its longitudinal axis. This can include unidirectional or reciprocal rotation or oscillation. In one presently contemplated embodiment, a circumferential gear is mounted around the fiber, and a small driving gear is engaged with the circumferential gear. The small gear may be unidirectionally or reciprocally rotated, or the small gear may be oval or elliptical in shape so as to oscillate the fiber about its longitudinal axis.

The angular displacement of a optical fiber can be employed with other optical fiber systems that produce a hollow cone or ring of radiant laser energy. For example, the proximal end portion of an optical fiber may define a proximal end surface oriented so that it is substantially perpendicular to the proximal end longitudinal axis. Laser radiation can be directed at an oblique angle into the proximal end surface of the optical fiber such that the radiation passing into the optical fiber strikes the cylindrical wall of the fiber with an angle of incidence greater than the critical angle for total internal reflection. The laser radiation passing into the optical fiber is reflected internally along the circumference of the fiber and is emitted from the fiber distal end surface in a substantially hollow cone configuration. The angular displacement of at least a portion of the length of the optical fiber will serve to reduce circumferential variations in the spatial radiation pattern of the ring-like beam along its radial path.

Still another aspect of the present invention employs a modification of the distal end of an optical fiber which may have a proximal end surface normal to the longitudinal axis for receiving laser radiation

directed along the axis to the proximal end surface. In particular, the distal end of the optical fiber from which the radiation is emitted is substantially conical. Preferably, the distal end has a right cone configuration, and the radiation is emitted in a hollow beam, defining a "halo" on an incident surface. Again, angular displacement of the fiber may be employed to eliminate variations in radiation intensity around the beam.

Another form of the present invention contemplates a unique process and system for controlling the application of radiation to a selected site. In particular, laser radiation is directed from a distal end portion of an optical fiber to irradiate the site with a hollow conical radiation beam or with an annular, substantially cylindrical radiation beam. The distance between the fiber distal end surface and the material is determined. Then the radiation intensity and duration is automatically adjusted in response to the distance determination. The material at the site is sculpted with the beam by moving the fiber distal end laterally and/or axially as desired.

The distal end portion of the fiber can also be tilted relative to the surface of the material to define a generally oval or elliptical irradiation pattern on the material, or any other pattern approximating a conical section or a portion thereof.

Another aspect of the method includes the step of positioning a distal end portion of at least one optical fiber adjacent to a target site. The distal end portion of the fiber has a distal end surface for emitting the laser radiation in the vicinity of the site. Laser radiation is directed into the optical fiber. The optical fiber distal end portion is moved adjacent the surface of the material at the site in

directions generally laterally of the emitted radiation. At least one of the following steps is effected in response to at least one of the other of the following steps: (1) controlling the intensity of the laser radiation, (2) controlling the distance of the fiber distal end surface from the material, (3) controlling the period of time during which the material is irradiated with laser radiation, and (4) controlling the angle of the fiber distal end surface relative to the surface of the material.

These controlled steps can be effected with radiation supplied in a variety of beam shapes or configurations (e.g., solid cylindrical or ring-like) from a variety of types of optical fibers (e.g., (a) a single, solid, optical fiber, (b) a single, hollow, optical fiber, (c) a plurality of solid, optical fibers arranged in an annular bundle, (d) a fiber or plurality of fibers having an angled end for emitting radiation, or (e) one or more optical fibers at whose distal end a section of hollow optical fiber is positioned, the section of hollow optical fiber being sufficiently long to obtain a generally uniform hollow beam or ring emission of laser energy from the distal surface thereof.) The laser beam emitting distal end of the fiber optic can be manipulated by mechanical means. The emitted beam can be manipulated by mirror systems, or the like.

Numerous other advantages and features of the present invention will become readily apparent from the following detailed description of the invention, from the claims, and from the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings that form part of the specification, and in which like numerals are

employed to designate like parts throughout the same,

FIG. 1 is a fragmentary, side elevational view, partly in cross section, showing the distal end portion of a laser delivery device embodying the present invention;

FIG. 2 is a cross-sectional view taken generally along the plane 2-2 in FIG. 1;

FIG. 3 is a reproduction of a developed photographic paper image of a plurality of ring-like irradiation patterns, such as halo R illustrated in FIG. 2;

FIG. 4 is a reproduction similar to FIG. 3 but showing the resulting irradiation patterns when the optical fiber distal end portion is tilted so as to create an elliptical ring configuration;

FIG. 5 is a fragmentary, diagrammatic, and partially schematic side elevational view of an alternate embodiment of an optical fiber embodying the present invention; and

FIG. 6 is a diagrammatic, partially cross-sectional view of another modified form of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The apparatus of the present invention is embodied in a laser delivery device which, in one preferred form, can be advantageously employed for applying radiant laser energy in a ring-like pattern to a selected body site, e.g., the cornea of an eye, in an efficient manner that minimizes trauma adjacent to the site. Such a device can be operated to irradiate a body site or other target with a hollow beam of laser energy of a desired shape and intensity in a controlled manner so as to minimize the likelihood of damage to adjacent tissue while effecting the desired ablation,

coagulation, cutting, or the like. The device is particularly suitable for use in the fields of ophthalmology, angioplasty, urology, and gynecology, for example.

The device, which can be designed to illuminate the target site with low powered laser energy in a ring-shaped pattern, for example, using a helium neon or HeNe laser, has many applications in surgery.

The generated hollow laser beam can also be used in a variety of manufacturing or industrial procedures for cutting, annealing, etc.,

While this invention is susceptible of embodiment in many different forms, this specification and the accompanying drawings disclose only one specific form as an example of the invention. The invention is not intended to be limited to the embodiment so described, however. The scope of the invention is pointed out in the appended claims.

The apparatus of this invention may be employed with suitable conventional laser sources and coupling systems therefor, the details of which, although not fully illustrated or described, will be apparent to those having skill in the art and an understanding of the necessary functions of such devices. The detailed descriptions of such devices are not necessary to an understanding of the invention and are not herein presented because such devices form no part of the present invention.

Referring now to FIG. 1, the apparatus of the present invention entails a lens for focusing laser energy from a laser (not fully shown) into the proximal, beveled end of an optical fiber, the distal end of which is positioned opposite a target tissue on the surface of a body or within a body lumen or cavity or in a surgically created area or passage. In some

applications, such a fiber system may be inserted through an endoscope, cannula, hollow needle, or other surgical instrument (not illustrated). The cavity into which the fiber system 10 may be inserted could be a natural or surgically created lumen, cavity or passage in body tissue. For example, the tissue may define a lumen or other cavity in the body or organ. A surgically created passage or area could be produced by a needle, by a scalpel in abdominal surgery, in an open procedure or by a trocar in a laparoscopic procedure.

Typically, the cavity into which the catheter is inserted, or the surface tissue at which the laser energy is directed, may be characterized as defining a body site containing a material which is to be altered by application of laser radiant energy. The material may be a part of the tissue <u>per se</u> or may be an altered form of the tissue, such as cancerous tissue. The material could also be an additional deposit on the tissue. For example, such a deposit may be a clot, fat, or arteriosclerotic plaque.

The fiber system 10 includes an optical fiber 20 which functions as an elongated, laser energy transmitting conduit. The optical fiber 20 is adapted to be coupled at its proximal end to a focusing lens and mounting frame or assembly 22 which in turn is coupled to a laser energy source 26 that generates and supplies radiant laser energy to the fiber 20.

The terms "laser energy", "laser radiation", "laser beam," and variants thereof as used in this specification disclosure and in the claims will be understood to encompass a broad range of radiation modes, pulsed or continuous wave (cw), as well as frequencies, characteristics, and energy densities or fluxes.

The laser radiation may be suitably produced

by a conventional laser and may include infrared radiation (IR) and ultraviolet radiation (UV), as well as visible laser light. Examples of laser types that can produce suitable energies include: excimer, argon, neodymium:yttrium aluminum garnet (Nd: YAG), frequency-doubled Nd:YAG (KTP laser), holmium:yttrium aluminum garnet (Holmium:YAG) and erbium:yttrium aluminum garnet (Erbium:YAG), and the like. Likewise, laser energy emitted in the so-called transverse electromagnetic wave (TEM) mode can be utilized. Particularly well suited is the cylindrical TEM_{01}. mode made up of two TEM_{01} modes, as well as the TEM_{03} mode and the TEM_{04} mode.

Conventional means (not illustrated in detail) may be employed for injecting the radiant laser energy to the assembly 22. Such means usually constitutes a coupling system between the laser source 26 and the assembly 22. The design, construction, and operation of laser sources and coupling systems are well known in the art and are not described in detail herein. The details of the design, construction, and operation of such laser sources and coupling systems form no part of the present invention.

The fiber 20 is a single, solid, elongate, unitary, optical fiber having a cylindrical core 30 which may be made of glass or silica quartz. In certain embodiments, such fibers can have a high hydroxy (OH) content, for transmission of excimer laser energy, or a low OH content, for transmission of Holmium:YAG laser energy.

In another embodiment, fibers of zirconium fluoride, sapphire or other crystals can be used to transmit erbium:yttrium aluminum garnet (Erbium:YAG) radiation or other infra-red wavelengths of light. Alternatively, in some applications, the fiber core 30 may be formed from polymeric materials such as, for

example, poly(methylmethacrylate) or polystyrene. The diameter of the core is preferably between about 0.1 mm. and about 1.0 mm. In one contemplated embodiment of the present invention, the diameter of the core 30 is preferably in the range of about 0.3 mm to about 0.6 mm.

In a preferred embodiment, an outer cladding 34 is disposed to cover the outer cylindrical surface of the core 30. The cladding material has a refractive index which is lower than the refractive index of the fiber core 30. The material employed for the core outer cladding 34 is selected on the basis of the refractive index relative to the core refractive index such that the laser radiation is confined within the fiber core with a minimum attenuation.

Examples of suitable cladding materials include silicone, silica, glass, plastic, or air. Plastic material suitable for cladding includes polymethylmethacrylate or a mixture of polymethylmethacrylate and polystyrene. The thickness of the cladding 34 may be about 0.1 mm, for example. In one contemplated embodiment, the cladding 34 is air.

Various optical fibers that may be suitable for particular applications are commercially available. For example, a fiber optic having a core diameter of 0.4 mm is marketed under the designation Med 400 by Quartz Products Corporation of Plainfield, New Jersey. A 0.6 mm diameter fiber optic is commercially available under the designation HCT 600 from Ensign Bickford Co., Connecticut, U.S.A.

The power that can be transmitted along optical fiber varies with the size of the fiber. Utilizing the above-described HCT 600 fiber optic a medical device embodying this invention can transmit as much as about 60 watts continuous power from a Nd:YAG laser source.

Although not necessary in all applications, a protective sheath (not illustrated) may be disposed around the outer cladding 34. The sheath may be, for example, polyethylene or a polyamide with a thickness of about 0.2 mm.

Finally, in some applications it may be desirable to include an outer tubular covering (not illustrated), instead of, or in addition to, the sheath. The covering may be a synthetic resin polymer such as the polymer sold under the trademark TEFLON. Other materials that may be used for the covering include silicone rubber, natural rubber, polyvinyl chlorides, polyurethane, copolyester polymers, thermoplastic rubbers, silicone-polycarbonate copolymers, polyethylene ethyl-vinyl-acetate copolymers, woven polyester fibers, or combinations of these.

The wall of the fiber system 10 may be reinforced. Further, radiopacity can be obtained by incorporating lead or barium salts into the wall of the catheter.

The fiber 20 has a distal end portion 42 extending along a distal end longitudinal axis 46. The distal end of the fiber 20 has a generally planar surface 47 that is perpendicular to the axis 46 and that functions to emit the laser radiation. If desired, the distal end portion 42 may be received in a rounded tubular sapphire, glass, quartz or Pyrex cap (not illustrated) that is substantially transparent to the radiation.

The laser radiation is transmitted into the fiber 20 at the proximal end of the fiber which is retained in the focusing lens and mounting assembly 22. The assembly 22 defines a bore 68 for receiving the proximal end of the fiber 20. The assembly 22 may be fabricated from a suitable material, such as stainless

steel or a polymeric material. The fiber 20 may be retained within the bore 68 by a suitable friction fit or by some other fastening means, such as, for example, adhesive or the like.

The proximal end of the fiber 20 is characterized as defining a proximal end longitudinal axis 66. The proximal end portion of the fiber 20 defines a beveled proximal end surface 70 which is oriented at an oblique angle A relative to the longitudinal axis 66.

A focusing lens 80 is held within the assembly 22 generally axially adjacent the angled surface 70. To this end, the assembly 22 includes an annular channel 82 for receiving the lens 80, and the annular channel 82 opens to a frustoconical passage 84 which is axially aligned with, and communicates with, the bore 68. A retaining clamp, ring, or seal 88 is preferably provided on one side of the lens 80 to help retain the lens 80 in position.

The lens 80 may be a suitable conventional focusing lens which is bounded by two refracting surfaces oriented about a common optic axis. The lens optic axis is either parallel to, or coincident with, the fiber proximal end axis 66. The axis 66 and the coincident optic axis of the lens 80 may be characterized as being oriented at an acute angle B relative to a plane N that is normal to the end surface 70.

The lens 86 functions to focus the laser radiation as schematically illustrated in FIG. 1 by the converging rays 92. The radiation incident on the beveled surface 70 is refracted generally toward the fiber exterior surface or cladding 34 on the circumference of the fiber 20 in accordance with the well-known principles of plane surface refraction and

total internal reflection.

Specifically, where the medium adjacent the beveled surface 70 (between the surface 70 and lens 80) is air (or some other medium having a smaller index of refraction than the optical fiber core 30), the angle of refraction at the surface 70 within the core 30 is less than the angle of incidence, and a radiation ray passing through the surface 70 is bent toward the plane N that is perpendicular to the surface 70.

Further, in the core 30, the radiation striking the cladding 34 with an angle of incidence greater than the critical angle will be transmitted by multiple, total internal reflections along the length of the fiber 20. The numerical aperture (i.e., the product of the index of refraction of the medium adjacent the surface 70 and the sine of one half of the acceptance cone angle) is equivalent of the square root of the difference between the square of the index of refraction of the core 30 and the square of the index of refraction of the cladding 34. This specifies the maximum angle within which the light is accepted into and conducted through the fiber 20. Of course, a skew ray of the radiation striking the cladding 34 within the fiber 20 will have a greater angle of incidence than the meridional rays, and the numerical aperture for such a skew ray is larger than that for meridional rays. A range of acceptance angles between about 30° and about 60° is desirable; a 45° angle approaches optimum.

It will be appreciated that the use of the novel bevel configuration on the fiber 20 permits the laser energy to be launched into the fiber to permit a meridional angle filling of the fiber without the need for any off-axis launching of the laser energy.

As described above, the proximal end portion of the fiber 20, assembly 22, and lens 80 function

together in combination as an intermediate "coupling means" for transferring the laser energy from the laser source 26 to the fiber 20. The radiation emerges from the fiber distal end surface 47 as a hollow cone which is schematically illustrated in FIG. 1 by the rays 94. An imaginary plane P oriented normal to the distal end longitudinal axis 46 would be intersected by the hollow cone of rays 94 to define a ring-like irradiation pattern or halo R as shown in FIG. 2.

The radiation pattern R can be employed on the surface of a body or within a body lumen, cavity or surgically created passage, to subject the tissue forward of the fiber 20 to a circumferential hollow beam of energy. This can be therapeutically useful in ophthalmology, angioplasty, urology, gynecology, etc., and can also be useful as an aiming beam in surgery. The device 10 may also be incorporated in a tool useful in manufacturing processes for annealing the inside of tubes, cutting circles, and the like.

FIG. 3 is a reproduction of images generated on a sheet of exposed photographic paper which was subjected to a number of separate, hollow, conical beams, e.g., pulses of radiation (such as illustrated by rays 94 in FIG. 1). FIG. 3 shows a plurality of patterns R which each correspond substantially to the irradiation pattern R illustrated in FIG. 2. Each pattern R was produced by aiming an optical fiber, such as the optical fiber 20 illustrated in FIG. 1, at the developed photographic paper sold in United States of America under the designation ZAP-IT™ by Kentec Corporation, 4 Depot Street, Pittsfield, NH 03263 U.S.A.

The laser radiation was produced with a holmium:yttrium aluminum garnet laser operating at a wavelength of 2.1 microns and generating 200 millijoules at 5 pulses per second transmitted through an optical

fiber having a diameter of about 400 microns with a proximal end surface defining about a 60° bevel (corresponding end surface 70 in FIG. 1 wherein the angle B is about 60°).

As the radiation-emitting distal end of the optical fiber was moved closer to the exposed photographic paper (analogous to moving the fiber end 47 closer to the plane P illustrated in FIG. 1), the diameter of the ring pattern decreased. Eventually, the pattern ceased to display a discernible, non-irradiated, circular, center region so that the irradiation pattern appeared to be a generally solid, circular pattern indicated by the reference letter S in FIG. 3.

The distal end of the optical fiber can be tilted relative to the plane of the target site. For example, and with reference to FIG. 1, the distal end surface 47 can be oriented at an oblique angle relative to the plane P. This produces a generally elliptical ring configuration with a greater energy density or flux occurring at those portions of the pattern on the target site which are closest to the angled emission surface 47.

FIG. 4 illustrates such elliptical configurations of the irradiation pattern. FIG. 4 is a reproduction of the exposed ZAP-IT™ brand paper described above which has been subjected to laser radiation from the above-described holmium: yttrium aluminum garnet laser. The radiation-emitting end surface of the optical fiber was tilted at an oblique angle to the plane of the photographic paper to produce the elliptical, ring patterns designated by the reference letter E.

According to another aspect of the invention, the conical beam can be emitted directly from the laser, which is positioned opposite the target and the

direction of the conical beam from the distal end of the fiber can be altered by conducting it through a path defining means, such as a microscope-like device with mirrors or an articulated arm with mirrors, as is known in the art. This is particularly desirable in the case of certain lasers emitting light energy at a wavelength which is difficult or impossible to transmit through conventional optical fibers, such as the argon fluoride (excimer) laser, the erbium:YAG laser, the CO laser, and the CO_2 laser, and the like.

According to a novel method of the present invention, the distal end portion 42 of the cylindrical optical fiber 20 is positioned opposite a tissue on the surface of the body or in a confined space with the distal end surface oriented for emitting the laser radiation in the vicinity of the target or site.

The proximal end portion of the fiber 20 is positioned to extend along the proximal end longitudinal axis 66 with the beveled end surface 70 oriented at an oblique angle A relative to the axis 66 for receiving the laser radiation.

The radiation is focused on the beveled surface 70 through the focusing lens 80 which is positioned relative to the proximal end surface 70 with the optic axis of the lens 80 being oriented either generally parallel to, or coincident with, the proximal end longitudinal axis 66. The laser radiation passes through the lens 80 and is transmitted into the fiber 20 where it is refracted and reflected internally along the Circumference of the fiber until it is emitted from the fiber distal end surface 47 in a substantially hollow cone configuration.

In a preferred form of the method, the fiber 20 is incorporated in a fiber system which is advanced to the target tissue to position the distal end of the

fiber 20 positioned at a selected axial location so as to be able to irradiate the body site.

The fiber system may be positioned visually or with the aid of fluoroscopy or ultrasound. In some treatment procedures, the fiber system may be advanced through an endoscope, cannula, hollow needle, or other surgical tool.

If the fiber system is inserted through an endoscope, cannula, hollow needle, or other surgical tool, then fluids may be infused about the fiber system body through the main passage in the tool or through a separate channel in the tool provided for that purpose. The fluids can include flushing fluids or treatment fluids, such as saline, a glycine solution, sorbitol-mannitol solution, sterile water, gases (such as carbon dioxide), and oxygen bearing liquids. Agents or drugs, such as an anti-coagulant, anti-spasmodic, anti-vasoconstrictive, or others, can be infused along with the fluid. Suction could also be effected through the endoscope or other tool.

Another aspect of the present invention relates to the production of radiation in a hollow cone configuration from the end of an optical fiber having a unique shape. FIG. 5 illustrates such an optical fiber 200. The fiber 200 is a cylindrical, solid, optical fiber which includes a proximal end portion defining a proximal end surface 270 and a distal end surface 247.

The fiber 200 may be fabricated from the same materials as described above with reference to the fiber 20 illustrated in FIG. 1. In the preferred form, the proximal end surface 270 of the fiber 200 is oriented so that it is generally normal to the proximal end longitudinal axis 266. The distal end portion of the fiber 200 extends along a distal end longitudinal axis 249. When the fiber 200 is oriented in a straight,

linear configuration, the axes 266 and 249 are collinear.

The distal end surface 247 defines at least one generally conical configuration with the base of the cone being oriented generally perpendicular to the distal end longitudinal axis 249. Preferably, the distal end surface 247 defines a right circular cone with its vertex lying on the distal end longitudinal axis 249.

Laser beam is directed into the fiber's proximal end surface 270, and preferably the radiation is directed generally perpendicularly to the proximal end surface 270. The laser radiation is transmitted through the fiber 200 and is emitted from the conical distal end surface 249 in a substantially hollow cone configuration. The emitted radiation, when impinging upon a generally planar target surface that is normal to the distal end longitudinal axis 249, defines a ring-like irradiation pattern or halo R. Other irradiation patterns resembling a conical section or a portion thereof are produced as the longitudinal axis 249 is inclined at an angle less than 90 degrees relative to the target surface.

The laser radiation may not be a uniformly emitted in a hollow cone configuration from the optical fiber distal end. This non-uniformity may be due to manufacturing and/or assembly tolerances, small variations in material quality or composition, small variations in operating conditions, and the like. Thus, the intensity or flux of the radiation field in the ring-like pattern R defined at the target surface (as illustrated in FIG. 2) may be non-uniform with respect to angular or circumferential locations on the ring pattern. For example, with reference to FIG. 2, an annular portion or segment Z1 of the halo pattern R may

have a radiation intensity that is greater or less than the remaining portion of the ring pattern R. There may be one or more other annular portions, such as region Z2, in which the radiation intensity or flux would also differ from that in other portions of the ring pattern R.

In many applications, and where strict manufacturing, assembly, and operating tolerances are imposed, such variations may have a negligible effect with respect to the particular use of the radiation. However, depending upon general power levels, size of the ring pattern, and other factors, the angular variations in intensity of the ring pattern could be sufficiently significant so as to result in undesirably uneven or non-uniform effects on the target site tissue or other target material. Thus, it would desirable to provide a means for reducing, if not eliminating, the angular (circumferential) variations.

Also, where a central zone of ablation is required, rather than moving the fiber sufficiently close to the target tissue to create a solid or complete spot, since that close proximity may cause spattering of ablation byproducts and foul or damage the distal end of the fiber, it would be desirable to be able to describe a solid, central spot with a gradual lateral diminution of energy.

To this end, a novel system can be employed for providing an irradiation pattern that is substantially uniform at the center or perimeter over a period of time. Specifically, as illustrated in FIG. 6, at least a portion of the length of an optical fiber, such as an optical fiber 300, is angularly displaced about its longitudinal axis during a period of time in which the radiation is emitted from the fiber 300. The fiber 300 may have the same composition as the fiber 20

described above with reference to FIG. 1. The fiber 300 may have a proximal end configuration and a distal configuration as shown for the fiber 20 in FIG. 1 or as shown for the fiber 200 in FIG. 5. In any case, the fiber 300 is arranged to cooperate with the laser radiation source so as to effect emission of the laser radiation from the fiber distal end in a substantially hollow cone configuration.

A driven ring gear 350 is mounted to the circumference of the fiber 300 by suitable means (e.g., adhesive at 353). A drive gear 355 is engaged with the ring gear 350. The drive gear 355 is mounted on a shaft 357. The shaft 357 is driven by suitable means, such as a motor (not illustrated), to rotate the drive gear 355. The rotation of the drive gear 355 effects rotation of the ring gear 350 which in turn causes the fiber 300 to rotate relative to its longitudinal axis. The rotation may be a small angular displacement, and in the preferred form, the angular displacement is in the form of an oscillation of the fiber 300 (as indicated by the double headed arrow 359) as effected by the motor causing the drive gear 353 to oscillate (in the direction of the double headed arrow 360). In a presently contemplated form of operation, the fiber 300 would be oscillated between about 0° to about 360°. Further, if the laser radiation source is operated in a pulsing mode, then the oscillations are preferably synchronized with the laser energy pulse, and this could be effected with an appropriate stepping motor and a suitable control system 361 which may include an appropriate switch or switches mounted to a suitable conduit or enclosure 363 which isolates the 350, gear 353, and shaft 357 from the surrounding environment.

Only a portion of the length of the optical fiber 300 need be angularly displaced, and typically

only a distal end portion of the fiber 300 would be oscillated or otherwise angularly displaced about the distal end portion longitudinal axis during the irradiation process.

In ophthalmology, sculpting or remodeling of the cornea may be accomplished by emitting laser energy at a selected intensity at a predetermined distance from the cornea for a chosen period of time. In some instances it is desirable to retract, temporarily the epithelium of the cornea prior to the laser irradiation of the anterior surface of the cornea. By varying the radiation energy level, distance from the cornea, and/or period of time of laser emission, it is possible to vary the rate of ablation, vaporization, or coagulation and the size and depth of the irradiation area. By tilting the angle of the fiber distal end portion from a perpendicular position relative to a generally planar site, the laser energy can be emitted, for example, in an elliptical or parabolic configuration with a relatively greater amount of energy density and deeper ablation, vaporization or coagulation resulting at one end of the configuration than the other so as to create a bifocal effect.

The distal end portion of the optical fiber or catheter can be moved in directions generally laterally of the emitted radiation, either manually or mechanically, and preferably by a mechanical means directed by a computer to more accurately control the sculpting process. The depth of ablation or coagulation can be indicated by displaying the patent's corneal shape on a television monitor and, using a light pen, the desired pattern can be drawn upon the screen. When this is done in one or more planes, preferably at least two planes, the laser energy, duration of exposure, and distance from the cornea can be determined and the

energy applied as desired. For safety purposes, the computer can conduct a "dry run" and display the resulting shape of the cornea, compared to the original shape.

Such procedures can be employed, for example, to increase or decrease the curvature of the cornea. Also, these techniques may be employed to merely heat a site to effect localized shrinkage of the surface of the cornea in the shape of a ring or any other desired configuration by collagen cross-linking.

Curvature of the cornea, and thus the refractive properties of the eye, can be adjusted by either selective removal of corneal tissue and/or by selective denaturization of the corneal tissue. Removal of the corneal tissue may be effected in a controlled manner using hollow laser beam irradiation in the ultraviolet or infrared ranges in accordance with the present invention, while thermal denaturization of selected regions of the corneal tissue can be achieved using laser beam irradiation in the near-infrared range.

In the type of present laser delivery device that generates a hollow beam, an excimer or erbium:YAG laser can be coupled with a computer-controlled x-, y-, z-plane positioning system and used to change the refractive power of the cornea by modifying its outer contour.

Similarly, a thermal laser, such as Nd:YAG, suitably pulsed and/or frequency tripled (351 μm wavelength), holmium, erbium, or the like, again appropriately coupled with a computer-controlled x-, y-, z-plane positioning system, can be utilized to change the corneal refractive power by creating therewithin three-dimensional zones or regions of thermally denatured collagen. These three-dimensional zones or regions can have any desired configuration that modifies

the outer contour of the cornea and thus changes its refractive power. The foregoing techniques can be employed singly, or in combination, to effect the desired corneal sculpting.

Also, for corneal sculpting with the thermal technique the cornea can be pre-treated with certain color bodies that preferentially absorb the laser wavelength that will be applied. For example, riboflavin dye or the patient's own erythrocytes can be applied to the cornea for use in conjunction with an argon laser.

The laser energy can be delivered in a continuous mode as well as a pulsed mode, as desired. Depending upon the wavelength of the involved laser beam, which can be in the range of about 0.15 μm to about 11 μm, ablative photodecomposition as well as thermal denaturization or decomposition can be effected.

The applied power flux can be pulsed or continuous for corneal sculpting and can be in range of about 1 joule per square centimeter to about 10 joules per square centimeter.

When operating the laser beam in a pulsed mode, the energy of individual pulses can vary, usually in the range of about 1 millijoule to about 300 millijoules. The pulse duration can be in the range of about 10 nanoseconds to about 400 microseconds. The depth of corneal ablation per pulse can be in the range of about 0.1 micron to about 200 microns. Excimer laser power flux of 1 joule/cm^2 ablates corneal tissue to a depth of about 1 micron.

The distance between the optical fiber distal end surface and the material at the irradiation site can also be measured, as with infra-red distance determination techniques, sonar distance determination techniques, or other techniques. The measurement of the

distance can be input to an appropriate microprocessor or computer for effecting control of the intensity of the energy of the laser radiation, the duration of exposure of the site material to the radiation, and/or the location of the optical fiber distal end portion relative to the site.

The above-described control techniques may be applied to other optical fiber transmissions of laser radiation not only during ophthalmologic procedures but also during medical as well as non-medical procedures. Such control techniques need not be limited to use with the above-described solid, optical fiber which produces a hollow cone beam for irradiating a target site with a ring-like pattern. Indeed, the above-described control techniques may even be employed with an optical fiber that emits laser radiation in a generally solid, cylindrical beam that defines a spot zone on the target tissue.

Also, in another aspect of the method of the present invention, a plurality of solid, optical fibers (e.g., about 200 to about 500 having a diameter, for example, of between about 10 microns and about 50 microns) may be arranged in an annular bundle, as by packing the fibers in the annular space between a pair of concentric cylindrical sleeves. Such a construction may be employed to transmit a generally ring-like beam.

In addition, a sufficiently long section of hollow, optical fiber may be supplied at its proximal end with laser radiation from a solid, optical fiber extending from a laser in a manner so that the radiation is emitted from the distal end of the hollow, optical fiber in a ring-like beam.

With either an annular bundle of fibers or a single, hollow, optical fiber, the distal end may be tilted or angled relative to the surface of the material

at the target site so as to provide a generally elliptical, ring-like target area where the energy intensity may vary depending upon a selected location within the elliptical ring pattern.

Also, a solid, optical fiber may be similarly tilted relative to the target site for producing a generally solid, elliptical pattern on the site.

The distal, radiation-emitting end of the above-described annular bundle of fibers can be arranged in an angled or beveled configuration. Similarly, the end of the hollow, optical fiber may be cut to form an angled or beveled end. When the surface of such a beveled end is viewed in elevation in a direction normal to the longitudinal axis of the fiber(s), then it appears as an ellipse or oval shape.

It will be appreciated that the present invention provides a novel method and apparatus for efficiently controlling and directing radiation, including the transmission of radiation in a hollow cone or ring configuration, to a selected site which may be located in a confined space.

In accordance with the preceding discussion, further adaption and variations of the present invention will be readily perceived by practitioners of the medical instrumentation and manufacturing arts. Therefore, the present invention should be interpreted in accordance with the language of the following claims and not solely in accordance with the particular embodiments within which the invention has been taught.